ROQUETTE PHARMA SOLUTIONS-QUALITY

Roquette Pharma has been a leading supplier of sustainably sourced, pharmaceutical ingredients to the pharmaceutical industry for more than 50 years. We offer our partners and their customers uncompromising quality standards, and a transparent and secure supply chain from our raw materials to our finished products. As the world's leading supplier of mannitol, sorbitol, and dextrose, we apply validated processes and analytical compendia or validated methods to guarantee reproducibility of the quality of each product, every time. Because pharmaceutical products (APIs [Active Pharmaceutical Ingredients], excipients, and drug products) are critical to patient's safety and efficacy of related medicines, the industry is highly regulated and has strict procedures and standards to comply with. At Roquette, we comply and adhere to the industry's toughest quality standards and international guidelines, and as a responsible manufacturer of APIs and excipients, we guarantee quality and end products' stability, ensure safety of use and reliability as well as facilitate global regulatory filing.

ROQUETTE QUALITY STANDARDS FOR EXCIPIENTS FOR ORAL APPLICATIONS

- Vertically integrated supplier with transparency of the whole supply chain
- ISO 9001 certified for all manufacturing sites
- IPEC-PQG Good Manufacturing Practices Guide
- GDP compliance where applicable, EXCiPACT™ certified for Crest site in India
- Food grade: check with us for availability
- Multicompendial compliance where applicable
- Stability studies defining the shelf life
- Where applicable, regulatory files approved, such as Ch DMFs

ROQUETTE QUALITY STANDARDS FOR APIS FOR INJECTABLE/PARENTERAL AND ORAL APPLICATIONS

- Vertically integrated supplier with transparency of the whole supply chain
- ISO 9001 certified for all manufacturing sites
- GMP compliance (EU part II, US 21 CFR 210, ICH Q7)
- GDP compliance where applicable
- Multicompendial compliance
- Stability studies under ICH conditions defining the retest-date
- Controlled, validated and approved manufacturing processes by Competent Health Authorities
- Regulatory approved dossiers such as CEP, Global DMFs where applicable

ROQUETTE QUALITY STANDARDS FOR EXCIPIENTS FOR INJECTABLE/PARENTERAL USE AND FOR BIOPHARMA APPLICATIONS

- Vertically integrated supplier with transparency of the whole supply chain
- ISO 9001 certified for all manufacturing sites
- GMP compliance for excipients for parenteral use (EU part II, US 21 CFR 210, ICH Q7)
- IPEC-PQG Good Manufacturing Practices Guide for Biopharma Excipients
- GDP compliance where applicable
- Multicompendial compliance where applicable
- Stability studies under ICH conditions
- Controlled, validated and approved manufacturing process by Competent Health Authorities
- Where applicable, regulatory files approved, such as DMFs

YOUR TECHNICAL AND FORMULATION EXPERT

We support and help accelerate early-stage drug development and provide technical data and formulation guidelines easily accessible to you. For more information, visit our Pharma Virtual Lab.

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